



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 17 1998

Rec'd 3/26/98 jlb

Mr. Gregory M. Walker
Regulatory Counsel
Murdock Madaus Schwabe
Professional Products, Inc.
10 Mountain Springs Parkway
Springville, Utah 84663

Dear Mr. Walker:

This is in response to your letter of February 11, 1998 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act)). Your submission states that Murdock Madaus Schwabe Professional Products, Inc. is making the following claims, among others, for the product "Neuromins Pro:"

"Low levels of DHA have been correlated with changes in disposition, memory loss, visual function and other neurological conditions"

21 USC 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely various neurological diseases or conditions. These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 USC 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 153

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

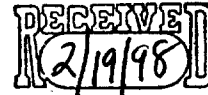
GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:3/4/98

init:GCF-1:DDorsey:3/6/98

f/t:HFS-456:rjm:3/11/98:docname:57233.adv:disc26

February 11, 1998



Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Murdock Madaus Schwabe Professional Products, Inc. wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Neuromins Pro. The dietary ingredient that is the subject of the statement is Docosahexanoic acid. The statement reads as follows:

"Fatty acid essential for mental and visual function. Docosahexanoic acid (DHA) is a fatty acid essential for mental and visual function. It is the primary structural fatty acid in the gray matter of the brain and retina of the eye and is important for signal transmission in the brain, eye and nervous system. Low levels of DHA have been correlated with changes in disposition, memory loss, visual function and other neurological conditions."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

MMS PRO



Gordon M. Walker
Regulatory Counsel

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Gordon Walker/Kahl-Pro-Neuromins

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